IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' NOTICE OF ADOPTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINION TESTIMONY OF DOUGLAS GRIER, M.D.

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motion they filed in relation to the general-causation opinions of Douglas Grier, M.D., in Wave 1, Dkt. 2022. *See* Pls.' Notice of Adoption (Dkt. 2773). The Court has ruled on that Wave 1 motion. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4547053 (S.D.W. Va. Aug. 31, 2016). Defendants Ethicon, Inc., Johnson & Johnson and, where applicable, Ethicon LLC (collectively, "Ethicon") respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed below and in accordance with this Court's August 31, 2016 Memorandum Opinion and Order.

ARGUMENT AND AUTHORITIES

I. Dr. Grier's Testimony Regarding the Safety and Efficacy Rates of Mesh Products Is Reliable.

Plaintiffs assert the identical arguments and record regarding Dr. Grier's opinions on the safety and efficacy rates of mesh products. This Court has already rejected Plaintiffs' argument that Dr. Grier must support his testimony regarding the safety and efficacy rates of mesh products with details from his clinical experiences. *In re: Ethicon Inc.*, 2016 WL 4547053, at * 3

("Here, Dr. Grier does not offer expert testimony about precise rates, so he is not necessarily required to detail his experiences."). Ethicon respectfully requests that this Court rule in the same manner in the Wave 3 cases and again deny Plaintiffs' motion with respect to the admissibility of Dr. Grier's opinions regarding the safety and efficacy rates of mesh products.

II. Because Dr. Grier Does Not Offer Any Opinions Regarding the Process of Designing a Product, Plaintiffs' Motion to Exclude His "Design Opinions" Should Be Denied as Moot.

Plaintiffs also assert the identical arguments and record regarding Dr. Grier's "design opinions" that they asserted in Wave 1. This Court has denied Plaintiffs' challenge to Dr. Grier's "design opinions" because Dr. Grier "has not expressed any opinions about the process of designing a product." *In re: Ethicon Inc.*, 2016 WL 4547053, at *3. Ethicon respectfully requests that this Court rule in the same manner in the Wave 3 cases and again deny as moot Plaintiffs' motion with respect to Dr. Grier's "design opinions."[1]

III. Dr. Grier Is Entitled to Testify about Risks of Implanting Mesh and Whether They Appeared in the IFU, and the Common Knowledge of Physicians Regarding Risks.

Dr. Grier's proposed testimony is consistent with this Court's orders. The Court has determined that Dr. Grier is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon Inc.*, 2016 WL 4547053, at *3. Further, the Court has expressed no opinion about expert testimony regarding "whether certain risks were common knowledge," and therefore has not precluded this expert testimony. *See, e.g.*, *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016) ("The plaintiffs' Motion focuses on whether Dr. Woods is

[1] To the extent Plaintiffs challenge Dr. Grier's qualifications and methodology regarding his testimony on the *safety and efficacy* of the TVT and Prolift designs, Ethicon incorporates and adopts its Opposition to Plaintiffs' Wave 1 motion (Dkt. 2179) at 2-4.

qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same, with respect to Dr. Drolet); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Serels); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Sepulveda-Toro); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493666, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Toglia); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Pramudji).

Dr. Grier is qualified to testify regarding the risks that are within the common knowledge of surgeons who perform pelvic surgeries. As detailed in Ethicon's Wave 1 motion, Dr. Grier has extensive clinical experience with native-tissue surgical procedures, surgical procedures involving mesh, and mesh repairs. Defs.' Opp. (Dkt. 2179) at 3. He also has taught over 300 courses for advanced surgical training of physicians for conditions such as stress urinary incontinence and pelvic organ prolapse. Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 2. And he has conducted research in the field of incontinence and bladder disorders, and has contributed to studies on the use of TVT abdominal guides and the TVT world registry published in the Journal of Urology in 2011. Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. In addition, Dr. Grier

relies on his review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and general knowledge as a pelvic-floor surgeon in reaching his opinions. Ex. 1, Grier 3/22/16 Dep. Tr. 326:23-330:20, 332:13-333:23; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 28-30.

As a practicing surgeon who went through years of medical training, has extensive clinical experience with pelvic floor surgeries, teaches other physicians about these surgeries, and keeps up with the medical literature, Dr. Grier is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic floor surgeries. Indeed, only a physician with such training and experience *could* testify as to common knowledge of surgeons who perform pelvic surgeries.

Because Dr. Grier has the qualifications and requisite foundation, he may offer his opinion that exposure/erosion is the only risk unique to mesh devices, and that degradation, shrinking, contraction or pore collapse, roping or curling, particle loss, cytotoxicity, excessive inflammatory response, and carcinogenicity are ***not*** risks associated with mesh devices. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 17, 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 18-21, 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 19-20, 34. In addition, Dr. Grier is qualified to testify that chronic pain and dyspareunia are generalized risks of mesh surgery and such risks are within the common knowledge of surgeons who perform

pelvic surgeries, including mesh implantations. Ex. 1, Grier 3/22/16 Dep. Tr. 19:12-21; 319:8-14, 332:18-25; 337:9-12.[2]

Thus, Ethicon respectfully requests that this Court deny Plaintiffs' motion to the extent it seeks to exclude Dr. Grier's testimony regarding the common knowledge of physicians regarding risks associated with pelvic floor surgery, and risks of implanting mesh and whether they were included in the IFU.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' Motion to Exclude the General Opinion Testimony of Douglas Grier, M.D. be denied.

Respectfully submitted,

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[2] Moreover, this testimony will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A, cmt. j. In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

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CERTIFICATE OF SERVICE

I certify that on October 11, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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